

## Contract Manufacturer Insert for Company's Consent Order

To add a Contract Manufacturer Order to a regular Consent Order, make the following changes to the Company's Consent Order:

### Preamble

1. Add "Consent Order for Contract Manufacturer" to bottom of cover page, as follows:

Consent Order, Consent Order for Contract Manufacturer,  
and Determinations Supporting Consent Orders

2. Add "Attachment C - Consent Order for Contract Manufacturer" to bottom of Table of Contents.
3. Add the following statement to the end of the Summary of Terms of Order: "A Consent Order for Contract Manufacturer is attached to extend these requirements to any Contract Manufacturers."

### Order

1. In the Testing section, add the following highlighted language to paragraph (d) of the Testing section:

"The Company is prohibited from manufacturing or importing, or causing another person to manufacture or import, the PMN substance beyond..."

2. Replace the Manufacturing section with the following insert:

### MANUFACTURING

(a) The Company shall not cause, encourage, or suggest the manufacture and/or import of the PMN substance by any other person outside the Company, except a Contract Manufacturer as described in paragraph (b).

(b) Notwithstanding paragraph (a), the Company may cause a "Contract Manufacturer" outside the Company to manufacture and/or import the PMN substance according to the following conditions:

(1) The Contract Manufacturer must be under contract to the Company to manufacture or import the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture or import.

(3) If, at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import of the PMN substance, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(A) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer.

(B) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(C) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substance, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture or import the PMN substance only upon written notification from the Agency.

(c)(1) Paragraph (a) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraph (a) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (a) expires in accordance with subparagraph (c)(1), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations.

(3) Paragraph (c)(1) shall not negate the effect of any fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2).

3. In Exposure-Based Orders, add the following highlighted language to the Risk Notification section:

(b) The Company must ensure that any Contract Manufacturers (as described in paragraph (b) of the Manufacturing section of this Order), persons who will receive the PMN substance from the Company, or any persons who have received the PMN substance from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.